

REMARKS

Status of the Present Application

The present application relates to the use of CG-containing immunostimulatory nucleic acid to modulate immune responses to antigens. Five claims are currently pending and a copy of the claims is attached herewith as Attachment B. The claims define the same invention as the claims of U.S. Patent No. 6,207,646 ("the Krieg '646 patent") and U.S. Patent No. 6,194,388 ("the Krieg '388 patent")¹.

In particular, claim 205 of the present application relates to a method for suppressing an allergic response to an antigen in a mammal by administering both an immunostimulatory nucleic acid and the antigen to the mammal. The subject matter of claim 205 is substantially the same as that of claim 3 of the Krieg '646 patent, which relates to a method for desensitizing a subject against an allergic reaction by administering to the subject a CG-containing immunostimulatory nucleic acid and the allergen.

In view of the presence of interfering subject matter, Applicants submitted a request for interference under 37 C.F.R. §1.607 on October 31, 2001, and a revised one on May 9, 2002, both of which contain a detailed explanation of the interfering claims. As set forth below, Applicants submit that all the pending claims in this application are allowable. Pursuant to 37 C.F.R. §1.606 and MPEP §2307.02, an interference should be declared if

¹ It should be noted that the Krieg '646 patent is incorrectly described, on its face, as having issued from a continuation application of the application leading to the Krieg '388 patent. In fact, the disclosures of the Krieg '646 and '388 patents are significantly different.

the application contains at least one allowable claim. Accordingly, Applicants respectfully request that an interference be declared.

Applicants further request expedited examination of the present application. Examination of an application in which applicants seek an interference with a patent shall be conducted with special dispatch under 37 C.F.R. §1.607 and MPEP §2307. Therefore, expedited examination, in which the present application is advanced out of turn for examination, is respectfully requested under MPEP §708.01(F).

Claim Amendments

Claim 205 has been amended to recite “the antigen provided as the antigen *per se* or as a polynucleotide encoding the antigen” instead of “the antigen encoded in the plasmid”. Support for this recitation can be found, for example, at page 6, lines 18-21.

No new matter has been introduced by these amendments. Entry of the amendments is requested.

Request for Continued Examination

Applicants hereby request continued examination of the present application under 37 C.F.R. §1.114.

Telephone Interview

Applicants' representatives wish to thank Examiner Q. Nguyen for extending the courtesy of discussing this Office Action with the undersigned by telephone on several occasions. The amendments and remarks reflect these discussions and suggestions made during the discussions.

Applicants have carefully considered the points raised in the Office Action and believe that the Examiner's concerns have been addressed as described herein, thereby placing this case in condition for declaration of interference.

Priority and Rejections of Claims 202-204 (Pages 2-24 of the Office Action)

The Office Action reiterates the issue of priority and rejections of claims 202-204 that were stated in the previous Office Action, dated March 15, 2002. Applicants have explained in detail the reasons under which these rejections should be withdrawn and claims 202-203 should be afforded the priority date of August 26, 1993. Therefore, in the interest of compact examination, Applicants respectfully request referral to the Amendment and Reply filed on May 9, 2002, for the priority issue and rejections of claims 202-204 addressed in the Office Action.

Rejection of Claim 205 (Page 25 of the Office Action)

The rejection of claim 205 under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for lacking antecedent basis, has been obviated as set forth below.

The Office Action states that claim 205 recites “the antigen encoded in the plasmid” while the only antigen referred to in the claim is an antigen that stimulates production of allergy-associated IgE antibodies, not antigen encoded in the plasmid (page 25 of the Office Action). Claim 205 has been amended to recite “the antigen provided as the antigen *per se* or as a polynucleotide encoding the antigen” instead of “the antigen encoded in the plasmid”. Therefore, the rejection is now moot, and its withdrawal is respectfully requested.

Rejection of Claim 206 (Pages 25-26 of the Office Action)

The rejection of claim 206 under 35 U.S.C. 103(a) in view of Felgner et al. (U.S. Patent No. 6,214,804) is respectfully traversed for the reasons set forth below.

Claim 206 is directed to a pharmaceutical composition for stimulating an immune response to an antigen, comprising pREP7 encoding the antigen and a pharmaceutically acceptable carrier. Felgner et al., on the other hand, relates to a method for delivering a polynucleotide into a cell, including the delivery of a polynucleotide to provide an immune response upon *in vivo* translation of the polynucleotide. As the Office Action points out, Felgner et al. disclose that the polynucleotide can take any number of forms without being limited to any particular polynucleotide. The Office Action admits that Felgner et al. do not specifically teach pREP7 encoding the antigen, but argues that it would have been obvious for one of ordinary skill to use pREP7 simply as a designer's choice because pREP7 was publicly available from Invitrogen (page 26 of the Office Action).

Applicants disagree. The fact that a claimed species is encompassed by a disclosed genus is not sufficient by itself to establish a *prima facie* case of obviousness. MPEP §2144.08; *in re Baird*, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994). Instead, it should be determined if one of ordinary skill in the relevant art would have been motivated to select the claimed species from the disclosed genus. MPEP §2144.08. Factors to consider include size of the genus, express teachings of the reference, structural similarity of any “preferred” species to the claimed species, teachings of similar properties, and predictability of the technology. *Id.* Here, the genus is vastly broad (all vectors that can be used to express a polypeptide). Felgner et al. do not provide any express teaching as to selection of a plasmid, do not disclose a preferred plasmid, nor point to any specific properties of pREP7 that are desirable. It was also not predictable from the technology on the priority date of the present application that pREP7 should be selected from the vast genus of plasmids. Therefore, it was not *prima facie* obvious to select pREP7 when any expression vector could be used for the purpose of Felgner et al.

Accordingly, claim 206 is not rendered obvious by Felgner et al. under 35 U.S.C. §103, and Applicants respectfully request that the rejection be withdrawn.

Request for Declaration of Interference

Pursuant to 37 C.F.R. §1.606 and MPEP §2307.02, an interference should be declared if the application contains at least one allowable claim. Therefore, upon an indication that claim 205 or 206 is allowable, consideration of an interference is appropriate. Count 1 for this interference would be claim 202 of the present application or

claim 7 of the Krieg '646 patent. Count 2 would be claim 205 of the present application or claim 3 of the Krieg '646 patent. The two proposed counts are set forth in Attachment C.

For the same reasons previously articulated in Applicants' requests for interference under 37 C.F.R. §1.607 submitted on October 31, 2001 and May 9, 2002, the following claims would correspond to the proposed counts:

Proposed Count 1: claims 202, 203 and 206 of the present application, claims 1-2, 4, 6-9, 13-19, and 21-22 of the Krieg '388 patent, as well as claims 1-2, 4, 6-11, 13-37, and 39 of the Krieg '646 patent; and

Proposed Count 2: claims 204 and 205 of the present application, and claims 3, 11, 12, 17, 21, 25, 27, 37 and 38 of the Krieg '646 patent.

CONCLUSION

In view of the above amendments and remarks, Applicants submit that all the claims of this application are patentable. Accordingly, Applicants respectfully request that an interference be declared employing the proposed counts set forth in Attachment C.

If the Examiner feels that a telephone interview would serve to facilitate resolution of any outstanding issues, he is encouraged to contact the undersigned at the telephone number below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 02-4800**, referencing docket no. 028723-306. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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ATTACHMENT A
VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

205. (Amended) A method for suppressing an allergic response to an antigen in a mammal susceptible to an allergic reaction to said antigen which stimulates production of allergy-associated IgE antibodies in the mammal, comprising parenterally administering to the mammal

(a) an effective amount of an immunostimulatory nucleic acid in a plasmid, said immunostimulatory nucleic acid comprising 5'CG3', wherein C is unmethylated, and

(b) an effective amount of the antigen provided as the antigen *per se* or as a polynucleotide encoding the antigen [or the antigen encoded in the plasmid].